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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,631	08/31/2001	Michael E. Rickey	00166.112-US00	8160

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WASHINGTON, DC 20004-2401

EXAMINER
WAX, ROBERT A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/942,631	RICKEY ET AL.
	Examiner	Art Unit
	Robert A. Wax	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 February 2004.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15, 18 and 20-87 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 74-87 is/are allowed.
- 6) Claim(s) 1-15, 18 and 20-73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

**DETAILED ACTION**

**INTRODUCTION**

1. Applicant's arguments in the amendment, filed February 26, 2004, with respect to claim 74 and those claims dependent therefrom have been fully considered and are persuasive. The rejection of claims 74-87 has been withdrawn. The rejection under 35 USC 103(a) of the remaining claims is, however, maintained.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-15, 18, 20-30, 32-50, 52, 54-60, 63-69 and 71-73 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. in view of Tice et al. ('330), Hodgman et al., Ed., Gutsell, Jr. et al. and Tracy et al.

This rejection was explained in the previous Office action.

4. Claim 31 is again rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. in view of Tice et al. ('330), Hodgman et al., Eds., Gutsell, Jr. et al. and Tracy et al. as applied to claims 1-15, 18, 20-30, 32-50, 52, 54-60, 63-69 and 71-73 above, and further in view of Thanoo et al.

This rejection was also explained in the previous Office action.

5. Claims 51, 53, 61, 62 and 70 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. in view of Tice et al. ('330), Hodgman et al., Eds., Gutsell, Jr. et al. and Tracy et al. as applied to claims 1-15, 18, 20-30, 32-50, 52, 54-60, 63-69 and 71-73 above, and further in view of Rickey et al. ('503).

This rejection was also explained in the previous Office action.

### ***Response to Arguments***

6. Applicant's arguments filed February 26, 2004 have been fully considered but they are not persuasive.

Applicants argue that the new claim limitation of washing after drying the finished microparticles is not taught by the prior art of record and this makes the instant claims patentable.

Examiner agrees that the specific limitation is not explicitly taught but disagrees that the limitation makes the claims patentable.

The section of Tice et al. ('330) quoted in the previous Office action is the reason the rejections are maintained. It is clear that the microparticles are finished at that point, although not dried. Tice et al. chose not to spend the time and energy on drying microparticles only to wet them again in the wash step. Rather, they proceeded right to the washing step. They certainly do not teach away from an additional step of drying

before washing but one of ordinary skill in the art would recognize that the solvent could be further reduced by a drying step prior to the extraction (washing) step of Tice et al.

Applicants' attention is directed to instant Example 3. In that example, the microparticles were not dried but subjected directly to the wash step. Sample 1 was extracted with ethanol, samples 2 and 3 were extracted with a mixture of ethanol and heptanes by adding ethanol to the heptane suspension of microparticles. Comparison of the results with the results obtained in Example 1, where the microparticles were dried before the extraction step, is instructive, even though no direct comparison is shown. The levels of residual solvent and the residual goserelin levels are very similar. This indicates that it makes no difference if you wash after drying or before. Applicants are invited to submit a declaration under 37 CFR 1.132 containing results of experiments making a direct comparison between processes wherein the only difference in conditions is extracting before or after drying. In the absence of such direct evidence, the extant data show no difference between the two and the choice of extracting before or after drying is not seen to make a patentable distinction. Thus, the above rejections are maintained.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax  
Primary Examiner  
Art Unit 1653